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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/786,627 | 04/17/2001 | Joseph R. Lakowicz | 2542-101 | 3516 |

7590

03/25/2003

Office of Research and Development
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EXAMINER

SNAY, JEFFREY R

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,627

Applicant(s)

LAKOWICZ ET AL.

Examiner

Jeffrey R. Snay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite in that it recites a number of chemical compounds identified only by a Tradename. Due to the possibility for future variation of Tradenames by their owners, the recitation of such constitute vague and indefinite terminology. Applicant should substitute actual chemical nomenclature for the recited tradenames to properly and definitely identify the chemical compounds intended.

Claim 18 is indefinite in that it improperly refers to a Figure of the specification. Applicant is reminded that the claims must be recited in a self-contained manner in order to clearly set forth the metes and bounds of the claim. It is additionally noted that the referenced Figure further renders the claim indefinite because it depicts an R group which is not identified.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method including an analyte dependent fluorophore having a ns decay time in combination with a reference fluorophore having a longer microsecond decay time, does not reasonably provide enablement for the presently recited claims without these limitations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims.

The specification clearly establishes that the disclosed invention contemplates the discovery by applicant that monitoring the amplitude modulation at intermediate frequencies of emission from a pair of fluorophores, one an analyte responsive fluorophore and of ns decay time and the second a reference fluorophore of a longer microsecond decay time, renders the detected emission of both fluorophores to be equivalent to the fraction of the total emission of the short lifetime fluorophore. See page 3, lines 13-15, and page 5, lines 1-11 of the specification. The disclosed method thus clearly requires these limitations as to the first and second fluorophores in order to achieve the contemplated result.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 6, 10, 14, 16, 23-28 and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowicz et al (US 5246867).

Lakowicz et al disclose an analytical method comprising irradiating a sample including a first fluorophore (donor) which is responsive to the analyte and a second fluorophore (acceptor). The sample is irradiated with intensity modulated light and the emission from the sample is analysed by phase-modulation to determine the presence of the analyte of interest, such as glucose. See particularly columns 5 and 6 of Lakowicz et al. A modulation frequency of 100 MHz is disclosed (see example 6). Specific embodiments of Lakowicz et al disclose glucose sensitive fluorophores bound to concanavalin A (column 5, lines 37-42). The irradiation can be performed with an electroluminescent device (column 5, lines 20-24). The clinical diagnostic method of Lakowicz et al would have been capable of characterization as any of a bioprocessing reaction, analytical chemistry process, or industrially or process control, as presently recited in claims 33-35 respectively.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general information related to fluorescence analysis.

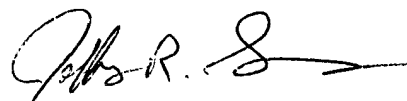
The prior art fails to teach or fairly suggest the method disclosed in the instant specification in which an analyte is detected via the amplitude modulation at intermediate frequencies of emission from a pair of fluorophores, one an analyte responsive fluorophore and of ns decay time and the second a reference fluorophore of a longer microsecond decay time, such that the detected emission of both fluorophores is equivalent to the fraction of the total emission of the short lifetime fluorophore.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Jeffrey R. Snay', with a long horizontal flourish extending to the right.

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs
March 20, 2003